(12) INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(72) Inventors; and
(75) Inventors/Applicants (for US only): SONDEEN, Jill, L.
[US/US]; P.O. Box 310048, New Braunfels, Texas 78131
(US). DREW, Guy, A. [US/US]; 14521 Waddesdon Bluff,
San Antonio, Texas 78233 (US).

(54) Title: SYSTEM AND METHOD FOR PROVIDING SERVO-CONTROLLED RESUSCITATION

(57) Abstract: The present invention provides a system and method for controlling resuscitation in a patient. In at least one em-
bodiment, the invention includes a fluid rate measurer, a controller electrically coupled to the fluid rate measurer, and a pump. The
controller is adapted to receive signals from a physiological monitor and controls the pump.

WO 2005/025646 A2

SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— *without international search report and to be republished upon receipt of that report*

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

System and Method for Providing Servo-Controlled Resuscitation

I.   Field of the Invention

The present invention relates generally to resuscitation, and more particularly to providing automated servo-controlled resuscitation.

II.   Background of the Invention

Studies have indicated that hemorrhage is one of the leading causes of death in conventional warfare. For example, some officials believe that hemorrhage accounts for approximately fifty percent of deaths occurring on the battlefield. It has been noted that effective first aid and proper fluid resuscitation strategies could prevent some of these casualties from occurring.

Therefore, resuscitation systems have been developed. For example, a typical resuscitation system may include a resuscitation pump which an operator (for example, a medic) utilizes to pump some type of revitalization fluid into the patient. Such systems often suffer from a variety of disadvantages.

For instance, as fluid is pumped into a patient based on the patient's condition, such pumps are often employed with a physiological device that can be utilized to monitor a patient's vital signs as the patient's condition changes. For example, it may be determined that a particular patient requires fluid resuscitation when his or her blood pressure falls below a particular low level. Until the blood pressure falls below the low level, the operator does not need to operate the resuscitation pump.

Similarly, when the patient's blood pressure reaches a particular high level, the resuscitation pump should not be operated. Although the user does not need to continuously operate the pump, it is imperative that the user activates the pump precisely when it should be activated (for example, when the patient's blood pressure falls below the particular low level) and deactivates the pump precisely when it should be deactivated (for example, when the patient's blood pressure reaches the particular high level). Otherwise, serious health risks may occur. For example, if the blood pressure rises too high, then a blood clot may be dislodged and bleeding may increase. On the other hand, if the blood flow is not high enough, an ischemia/reperfusion injury can occur, thereby possibly leading to brain damage, heart attacks and injury to other vital organs such as the liver, kidneys, and lungs.

Thus, the user must constantly and carefully monitor the physiological device to precisely determine when to activate and deactivate the pump. Such a task can be burdensome, as the user (for example, a medic on the battlefield) may be simultaneously responsible for several patients. The resuscitation process occurs over a long period of time (for example, a few hours) and the patient's status will fluctuate during this time, thereby resulting in fatigue on the part of the user and serious repercussions for the patient.

Yet another one of the drawbacks of traditional resuscitation systems relates to failure of the pump to maintain the pumping rate/level at which it was programmed to pump. For

instance, a variety of events may occur during operation of the pump that may cause the pumping rate of the pump into the patient to be altered. For example, an increased venous pressure may slow the pump flow rate of the resuscitation fluid, or the tube that transports fluid from its container to the pump may experience stretching, thereby impacting the accuracy of the pumping rate/level. Failure of the resuscitation pump to maintain the pumping rate/level may also lead to the above-referenced health effects. Other problems may also occur such as if a particular dose of the fluid is required, inaccurate pumping rate could lead to an overdose or underdose being given.

Therefore, in light of the foregoing, what is needed is an automated and accurate system for controlling resuscitation.

III.   Summary of the Invention

The present invention provides an automated system for controlling resuscitation in a patient. In at least one embodiment, the invention includes a fluid rate measurer, a pump, a physiological monitor, and a controller coupled to the fluid rate measurer, the pump, and the physiological monitor. The controller is adapted to receive signals transmitted by the physiological monitor and is capable of executing a servo control computer program module for controlling the resuscitation pumping to maintain those values of the desired physiological variable range and an error correction computer program module for performing error correction of the resuscitation pump based on a relation of an amount of fluid expected to be pumped and an amount of fluid that is actually pumped by the pump.

A method for controlling resuscitation of a patient connected to a physiological monitor, the method comprising: receiving a physiological signal from a physiological monitor, the physiological signal is indicative of a physiological variable, sending a pumping signal to a pump based upon whether the physiological variable is below a target range for the physiological variable, receiving a flow signal from a measuring device, the flow signal is indicative of the rate of resuscitation fluid is being pumped into the patient; and performing error correction of the pumping signal based on the difference between an amount of fluid expected to be pumped and an amount of fluid that is actually pumped.

In at least one embodiment, the invention further includes a calibration module for performing an initial fluid flow rate calibration to determine a relationship between pumping volume and pumping voltage. Such a calibration assists in assuring that the pump is accurately pumping.

IV.   Brief Description of the Drawings

The use of cross-hatching or shading within these drawings should not be interpreted as a limitation on the potential materials used for construction. Like reference numerals in the figures represent and refer to the same element or function.

Figures 1A and 1B illustrate block diagrams of exemplary systems of the present invention.

Figure 2 illustrates a specific exemplary embodiment of the system of the present invention.

Figure 3 illustrates a Graphical User Interface (GUI) depicting a servo-control resuscitation function according to at least one embodiment of the invention.

Figure 4 illustrates an exemplary line graph visual display representing results of an actual test of the system of the present invention.

Figure 5A is a flow diagram illustrating exemplary steps of an aspect of the present invention.

Figure 5B is a flow diagram illustrating exemplary steps involved in obtaining feedback from the system for error correction according to the present invention.

Figure 6 illustrates a GUI depicting the connection function according to at least one embodiment of the present invention.

Figure 7 illustrates an exemplary calibration setup system according to at least one embodiment of the present invention.

Figure 8 illustrates a GUI depicting the automatic pump calibration function according to at least one embodiment of the invention.

Figure 9 illustrates an exemplary portable system according to at least one embodiment of the invention.

V.   Detailed Description of the Drawings

A.   Overview of System/Software

Figure 1A illustrates a block diagram of an exemplary system 100 of the present invention. The system 100 may be utilized to automatically resuscitate a patient. In the embodiment of the invention illustrated in Figure 1A, the system includes controller 105, pump 110, fluid flow rate measurer 115, and physiological monitor 120. Figure 1B illustrates another exemplary embodiment of the invention that includes the controller 105, the pump 110, and the fluid flow rate measurer 115.

The controller (or means for controlling) 105 controls operation of the system. In at least one embodiment, the controller 105 is a mainframe computer, minicomputer, personal computer, personal data assistant (PDA), or processing device as would be known to those of ordinary skill in the art after being presented with the disclosure herein. The controller 105 may, for example, execute software modules of the present invention. The software modules allow an operator to enter values according to which the system operates (for example, fluid flow rate for the pump 110) to automatically control resuscitation of a patient.

The software modules of the present invention preferably include a servo-controlled resuscitation module and a feedback/error correction module. The feedback/error correction module serves as an error correction means. The servo-controlled resuscitation module serves as a controlling means for automatically controlling the pumping means based on signals received from the physiological monitor and signal received from the error correction means. In

at least one embodiment, however, the software modules of the present invention further include a connection/fluid rate calibration module (or means for calibrating fluid flow rate to determine a relationship between pumping volume and pumping voltage).

The pump (or means for pumping resuscitation fluid) 110 pumps fluid from a fluid container into a patient, thereby preferably resuscitating the patient. For example, in at least one embodiment, a tube extending from the container is connected to the pump 110. The pump 110 may be any resuscitation pump known to those of ordinary skill in the art. Examples of commercially available pumps include a MasterFlex roller pump (Cole Parmer Inc); a Power Infusion pump (Infusion Dynamics, Inc), a miniature IV resuscitation pump; or any standard hospital patient infusion pump in which two-way communication can be established with a computer. It should be noted in at least one embodiment that multiple pumps may be employed in the system of the present invention such that one pump pumps resuscitation fluid while a second or more pump(s) pumps medication or other material to the patient in addition to the resuscitation fluid.

The fluid flow rate measurer (or means for measuring a representation of fluid rate) 115 preferably determines the rate at which fluid is infused into the patient. Examples of the fluid flow rate measurer 115 include a flow meter that fits on the tubing, or a drip counter. The fluid flow rate measurer 115 may also be a balance 215 that is discussed in exemplary embodiments below.

The physiological monitor 120 monitors a physiological sign such as a vital sign (for example, arterial oxygen saturation, blood pressure, or heart rate). In at least one embodiment, the physiological monitor 120 includes a data acquisition system which can transmit physiological data such as systolic pressure to the controller. For example, the user may select to control the systolic pressure to 80 ± 2 mmHg, in which a low systolic pressure limit of 78 mmHg below which the controller would turn on the resuscitation pump and a high systolic pressure limit of 82 mmHg above which the controller would turn the pump off. Any other monitored variable could be used to, for example, maintain arterial oxygen saturation at 90 ± 2 percent or heart rate at 100 ± 10 beats per minute. After being presented with the disclosure herein, those of ordinary skill in the relevant art will realize that the physiological monitor 120 may be any physiological monitor known to those of ordinary skill in the art and may monitor a variety of types of bodily functions of the patient.

Figure 2 illustrates a specific environment in which an exemplary system 200 of the present invention may be utilized to resuscitate a patient. The exemplary system 200 preferably includes the controller 105, the pump 110, a fluid weight balance 215, and the physiological monitor 120. The pump 110 is preferably coupled to a patient 225 through, for example, fluid lines and communicatively coupled to the controller 105 via, for example, an RS-232 connection. The fluid weight balance 215 is also communicatively coupled to the controller 105. Finally, the physiological monitor 120 is coupled to the patient 225 and communicatively

coupled to the controller 105. Those skilled in the relevant art will realize that a variety of methods exist by which the components of the system 200 may be coupled together and to the patient 225. For example, the physiological monitor 120 may be coupled to the controller 105 by a communications cable or Wireless-Fidelity (Wi-Fi).

In the embodiment illustrated in Figure 2, the fluid weight balance 215 preferably holds a container of fluid to be infused into the patient 225. For example, in at least one embodiment, the fluid weight balance 215 weighs a medical IV bag having hydration (or resuscitation) fluid. The fluid weight balance 215 may be any fluid weight balance known to those of ordinary skill in the art such as a Mettler balance with an analog or digital output that is provided to the controller 105.

Regardless of whether the present invention is implemented in hardware or software, an operator of the system of the present invention interacts with the system via at least one graphical user interface (GUI) executed on the controller 105. In at least one embodiment, the present invention includes a GUI for providing a main menu to an operator of the system. In such an embodiment, the GUI includes a list of menu options from which an operator may choose. The modules discussed above will be discussed below in exemplary implementations of the invention.

B.   Servo-controlled Resuscitation Module

After the pump 110 has been calibrated, the operator preferably selects a resuscitation function option from the main menu GUI, thereby executing the servo-controlled resuscitation module of the present invention. For instance, Figure 3 illustrates a GUI for the servo-controlled resuscitation module. Before the system of the present invention may operate, in at least one embodiment, the operator preferably selects a control variable, for example, a physiological variable such as systolic pressure as measured by the physiological monitor 120 attached to the patient, and enters a range for the control variable. The control variable range preferably determines when fluid will be infused into the patient. For example, as shown in Figure 3, the operator has indicated a control variable range of 78.00 to 82.00. Thus, "on" data field 305 includes the value "78.00," and "off" data field 310 includes the value 82.00. Data fields 305 and 310 respectively are examples of means for allowing an operator to specify a low/high value for a physiological variable range.

Thus, the system will automatically activate when the physiological control variable is below a value of 78.00 and in one embodiment will continue to operate until the variable reaches a value of 82.00. Upon reaching the value of 82.00, however, the system will cease operation, as the endpoint (that is, the "off" value) has been obtained. In at least one embodiment, a trend line of the variable is electronically graphed, as shown in control variable graph section 320, and a current reading for the variable is displayed in window 325 (for example, every five seconds). In at least one embodiment, the control variable must read lower than the value entered into the "on" data field 305 for a number of cycles such as two data

collection cycles (or for approximately ten seconds) to prevent the pump from cycling too frequently if there are transient changes. Similarly, the control variable must read higher than (or the same as) the value entered into the "off" data field 310 or be present in the operator selected range before the system deactivates.

In at least one embodiment, in addition to entering a range for the control variable, the operator also selects or enters a constant infusion rate and a specific gravity of the fluid used (the purposes of which will be described herein below). In addition to these values, in at least one embodiment, the operator also preferably enters an "amount" value 350, a "delivery rate (ml/min)" value 375, a "pump direction" value 380, and a "specific gravity of fluid" value 385. The controller automatically keeps track of a "current" value 352, an "error" value 354, a "balance" value 356, a "start" value 358, a "run time" value 360, a "total (g)" value 365, and a "total (ml)" value 370. Each of these values will now be described in detail.

If the fluid measurer is a balance, the amount value 350 is preferably measured in grams. For other devices such as the flow meter or drip counter, the amount will be measured in the appropriate units (for example, ml/min or drips per minute, respectively). A positive value indicates that weight (fluid) will be added to the fluid weight balance (hemorrhaging simulation). A negative value indicates that fluid will be removed from the fluid weight balance (infusion). In at least one embodiment, the field into which this value is entered is disabled while fluid is actually being delivered. The current value 352 indicates the current amount of fluid delivered in grams for the current resuscitation session. In at least one embodiment, a cylinder bar status 390 is provided as a visual indication of how much fluid has been delivered for the given resuscitation session. The error value 354 indicates the delivery system error based on the difference between requested and actual delivery of fluid. A positive value indicates that the system has exceeded the appropriate delivery (too much). A negative value indicates that the system has not provided enough delivery.

The balance value 356 indicates the actual present weight of fluid in grams as indicated on the balance. The start value 358 indicates the weight on the fluid weight balance in grams at the start of a resuscitation session. The run time value (preferably measured in hours, minutes, and seconds) 360 indicates the total amount of time fluid has been delivered and is accumulative for all resuscitation sessions. The total (g) value 365 indicates an accumulative total weight in grams of fluid delivered for all resuscitation sessions. The total (ml) value 370 indicates a cumulative total volume in milliliters of fluid delivered for all runs. The specific gravity of fluid value 385 is measured in grams per milliliter and is used to calculate the actual milliliters per minute delivered based on grams over time. Once a resuscitation session has begun, the field into which the value is entered is preferably disabled. By having the computer cumulate multiple resuscitation sessions, the bags of fluid can be changed during the procedure, as is often necessary, and the total amount of fluid administered is monitored.

Alternatively, the data fields relating to weight and information from a balance may be replaced by data fields relating to a flow meter, a drip counter, or other fluid measurement devices as one of ordinary skill in the art will appreciate based on this disclosure. These fields provide information to the operator as to the status of the system and the resuscitation.

The delivery rate value 375 indicates the rate at which fluid is to be delivered in milliliters per minute. In at least one embodiment, after a resuscitation session has begun, the field into which the value is entered is disabled, as its value can only be changed at the start of a resuscitation session. The pump direction value 380 indicates the pump's rotation as clockwise (cw) or counter-clockwise (ccw).

In at least one embodiment, the GUI for the servo controlled resuscitation module preferably includes a panel of main control buttons. For instance, the buttons may include "stop," "tare" (used to clear the current (g) for a particular resuscitation session and load a new start (g) for a new resuscitation session in a balance implementation), and "start."

In at least one embodiment, the GUI for the servo-controlled resuscitation module preferably includes an electronic prime button for providing an operator with the ability to remotely prime the resuscitation pump and fluid lines (that is, tubing) without having to actually adjust the actual pump. In at least one embodiment, the GUI further includes a prime directional control, a prime rate control, a prime start control, and a prime exit control. The default prime rate is preferably equal to the resuscitation delivery rate for a resuscitation session.

A status indicator preferably provides information to an operator relating to the resuscitation session (for example, fluid level percentages as related to the amount (g) entered for delivery) according to at least one embodiment of the invention using the balance implementation. The indicator preferably changes color according to the status of the system. Exemplary colors are: (1) grey (system is ready; operator must press the start button to begin); (2) green (system is running and fluid delivery is normal); (3) yellow (less than forty percent of fluid specified to be infused is remaining in the fluid container on the fluid weight balance); and (4) red (less than twenty percent of fluid specified to be infused is remaining in the fluid container, or the stop limit has been reached and more fluid must be added to the system). In at least one embodiment, the color red may also indicate that the balance is not ready. A visual indicator may also be provided to allow an operator to determine how much fluid has been delivered for a given resuscitation session. The indicator may change colors depending on the fluid status. When a new reading is performed and values updated accordingly, an update indicator is preferably provided in at least one embodiment.

In at least one embodiment, the results of a resuscitation session may be provided in an electronic graph, as illustrated in Figure 4. Systolic blood pressure variable 405 and weight of resuscitation variable 410 (in a balance implementation) are plotted on a line graph along with the time of day variable 415. As shown in Figure 4, the graph preferably shows the cumulative weight of the resuscitation fluid during a session. Marker 417 indicates when the resuscitation

session was started; marker 420 indicates when the resuscitation pump was turned off; marker 425 indicates when the resuscitation session was briefly paused to obtain a blood sample from a catheter; marker 430 indicates when the resuscitation pump was turned on and off around the target; and marker 435 indicates death of the patient.

The variables are preferably recorded in a text file and may be imported into another type of file (for example, Microsoft Excel) used to graph the data. In at least one embodiment, data is written to the text file every 5 seconds.

Additionally, any pattern of fluid administration (for example, an initially fast, then a slower rate as the target endpoint is approached) can be programmed into the computer for maximum flexibility. The system also saves all the data so that an accurate record of the fluid administered is automatically saved. Thus, in at least one embodiment, the system pumps according to data stored in a predetermined profile. For example, the profile data may include a target physiological range and infusion rates according to which the pump should operate.

The invention also includes a method for performing resuscitation as illustrated in Figure 5A. In step 550, the system receives a physiological signal from a physiological monitor, where the physiological signal is an indication of a physiological variable such as oxygen level, blood pressure, and pulse rate. Based on whether this physiological signal is below a target range for the physiological variable, a pumping signal (or control signal) is sent to the pump to activate it and pump resuscitation fluid into the patient as discussed above, step 555. The pumping signal is in the illustrated apparatus embodiments is a voltage, which level is determined based upon a look-up table for the particular pump and fluid line combination being used. In step 560, a flow signal is received from a measuring device such as the fluid rate measurer 115, where the flow signal is an indication of the actual rate that resuscitation fluid is being pumped into the patient. In step 565, a comparison is performed between the actual flow rate based on the flow signal and expected flow rate based on the pumping signal to determine an error correction value and thereafter adjust the pumping signal to bring into align the actual flow rate with the anticipated flow rate. An exemplary method for performing the error correction is illustrated in Figure 5B and discussed below.

C. Feedback/Error Correction Module

Although the resuscitation pump is preferably calibrated before a resuscitation session, a variety of types of problems may occur during a resuscitation session to cause the pump not to operate at the programmed rate. For example, venous blood pressure or fluid line constriction may increase the back pressure which may affect the pump's output, the resuscitation pump may clot during pumping of a substance such as blood, and/or operation of the pump may be affected by the various viscosities (thickness) of different fluids. To compensate for these operational effects on the resuscitation pump, a feedback/error control module is provided in the system of the present invention. In summary, the feedback/error control module of the present invention compares the level of fluid measured by the fluid flow rate measurer 115 with the level

of fluid expected if the pump was pumping at the set rate. In at least one embodiment, this comparison is performed and updated every five seconds.

Figure 5B illustrates a flow diagram for steps involved in providing feedback for the system of the present Invention in which a fluid weight balance 215 is utilized for the flow rate measurer 115. In step 505, an expected relation of volume and time (that is, the rate at which the user desires the pump to operate) according to which the system should operate is preferably entered into a system GUI, as described above in Figure 3. For example, in at least one embodiment, the relation is entered in milliliters per minute, as shown in Figure 3 (that is, delivery rate value 375). After being presented with the disclosure herein, those skilled in the relevant art(s) will realize, however, that the relation may be entered in any viable measurement.

In step 510, the expected relation of volume and time (e.g., milliliters/minute) is preferably converted to a pumping voltage according to which the resuscitation pump is operated. After being presented with the disclosure herein, those skilled in the relevant art will realize a variety of formulas and methods exist for converting the volume and time relation to a pumping voltage such as a look-up table or any other means for converting the expected relation of volume and time to a pumping voltage.

In step 515, a specific gravity of fluid value is received from the user. For instance, the specific gravity of fluid value 385 in Figure 3, measured in grams per milliliter, is preferably received by the system from the user of the present invention. The field into which the specific gravity of fluid value 385 is an example of means for receiving a specific gravity of fluid value.

In step 520, the specific gravity of fluid value is utilized to convert the expected volume relation to an expected fluid weight measurement. After being presented with the disclosure herein, those skilled in the relevant art will realize that a variety of formulas and other means for utilizing the specific gravity of a fluid value exist for converting the expected relation to an expected fluid weight measurement.

In step 525, an actual fluid weight measurement is received into one of the fields (that is, a means for receiving the actual fluid weight measurement) of the GUI. That is, the fluid weight balance, for example, preferably transmits a signal including a weight value 356 for the fluid resting on the balance to the controller.

In step 530, the actual fluid weight measurement received in step 525 is compared with the expected fluid weight measurement calculated in step 520. After being presented with the disclosure herein, those of ordinary skill in the art will realize that a variety of methods (or means for comparing the actual fluid weight measurement with the expected fluid weight measurement) may be used to conduct the comparison. If the two values do not agree, an error term is preferably calculated and a rate is determined based on the difference between the two values. The software to perform this step is an example of means for determining a rate. The resuscitation pump is then instructed to either increase or decrease its speed according to the

9

magnitude (that is, the value) and the direction of the error. When the error term equals zero (that is, there is no error), the pump is preferably instructed to pump at the set rate.

This error feedback method can work similarly for any device used to independently verify the accuracy of actual fluid dispensement (for example, the actual flow recorded by a flow meter will be used to generate an error term which will be used by the controller to adjust the flow rate of the system until the controlled flow rate equals the desired flow rate).

D.   System Connection/Fluid Rate Calibration Module

In at least one embodiment, prior to operation of the system, parameter values (for example, patient identification, date, body weight, or any other identifying information) are preferably entered into the appropriate areas of a demographics GUI of the system of the present invention. After the parameter values are entered, the software modules of the present invention preferably connect with the system 100, for example, the pump, the flow rate measurer, and the physiological monitor. For example, as shown in Figure 6, a GUI menu is preferably provided with a "connections" menu/option 610. The connections menu 610 includes options for connecting components of the system. For example, in at least one embodiment, the connections menu 610 includes a connect pump option 630, a connect balance option 635, and a connect pressure option 640. As shown in Figure 6, connecting a system component preferably includes three steps: (1) selecting the particular system component (for example, the pump or the balance); (2) selecting the particular communications port; and (3) pressing the connect electronic button. For instance, to connect the resuscitation pump to communications port, the operator selects the pump option 630 from the connections menu 610 and then selects the corresponding communications port to communicatively couple the pump device to the communications port via the software. As one of ordinary skill in the art will appreciate based on this disclosure, the initial set-up may be accomplished with automatic configuration such as plug and play.

After the parameter values are entered into the system and the system components are connected, in at least one embodiment the system further includes a calibration module which serves as a means for calibrating the fluid flow rate (that is, automatic calibration). Calibration is performed to calibrate the rate at which fluid flows from the resuscitation pump. For example, Figure 7 illustrates a basic calibration setup system 700 for calibrating the resuscitation pump. The calibration setup system 700 preferably includes a reservoir 705, a resuscitation pump 710, and a fluid weight balance 715. The reservoir 705 includes fluid and is connected to the intake of the selected tubing 717. The tubing 717 is routed through the pump 710 and into the receiving reservoir 716 on the fluid weight balance 715. In at least one embodiment, the operator preferably enters a variety of calibration parameters such as a tubing size value, a resuscitation pump direction value, a resuscitation pump cycle time value, a set point high value, and a set point low value. Appropriate calibration parameters would be programmed

specific for each kind of pump used (for example, the MasterFlex pump used in this example, the Power Infuser rotary pump, or any standard patient intravenous fluid or syringe pump).

Figure 8 illustrates an exemplary GUI 800 for entering the calibration parameters. In "tubing size" field 805, a value for the size and/or type of tubing to be used to pump fluid from the fluid weight balance is entered. For instance, as shown in Figure 8, the tubing size field 805 includes the value "L/S 16 : 1.60 <> 80". "L/S" refers to a specific type of biocompatible tubing, and the numbers following "L/S" refer to the tube manufacturer's (for example, Cole-Parmer) model number. The 1.60 and 80 are the minimum and maximum ranges in ml/min that the model of tubing is capable of pumping. Resuscitation pumps are dependent upon size and material of the tubing as to how accurately the pumps operate. The type of tubing preferably allows the fluid rate calibration function to determine the possible range of fluid delivery for the particular resuscitation pump. It should be noted that different pumps support different tubing sizes. Table 1 below indicates exemplary tubing sizes for a 100 RPM MasterFlex pump which provides greater accuracy at slow speeds and a 600 RPM MasterFlex pump that allows better accuracy at higher rates.

Table 2- Tubing Size vs. Pump RPMs

100 RPM MasterFlex Pump	600 RPM MasterFlex Pump
L/S 13 : 0.12 <> 6.0	L/S 13 : 0.60 <> 36.0
L/S 14 : 0.42 <> 21.0	L/S 14: 2.10 <> 126.0
L/S 16 : 1.60 <> 80.0	L/S 16 : 8.00 <> 480.0
L/S 25 : 3.40 <> 170.0	L/S 25 : 17.0 <> 1020.0
L/S 17 : 5.60 <> 280.0	L/S 17 : 28.00 <> 1680.0
L/S 18 : 7.60 <> 380.0	L/S 18 : 38.00 <> 2280.0
L/S 15 : 3.60 <> 180.0	L/S 15 : 18.00 <> 1080.0
L/S 24 : 6.00 <> 300.0	L/S 24 : 30.00 <> 1800.0
L/S 35 : 8.60 <> 430.0	L/S 35: 43.00 <> 2580.0
L/S 36 : 11.60 <> 580.0	L/S 36: 58.00 <> 3480.0

Similar look-up tables can be included that are specific for each model and manufacturer of pump and tubing. In a production version of the device, the controller would be matched with a discrete set of pumps or a particular pump and tubing sizes as part of a standard set of equipment for medics.

In at least one embodiment, in addition to entering tubing size, the size of the pump head is preferably entered. The fluid rate calibration module of the present invention utilizes the tubing size value and the pump head size value to index an electronic table to obtain possible fluid rate ranges for the specified pump head size and tubing size. For example, the software may determine that for the entered tubing size and pump head size combination, the pump is capable of pumping from a low range 820 of 2-32 ml/min to a high range 825 of 16-80 ml/min.

For each of the offered low range 820 (that is, means for allowing an operator to specify a low value) and high range 825 (that is, means for allowing an operator to specify a high value), the operator may specify exact points in the particular range according to which the pump will be operated. For instance, for the high range 825, the operator may specify a setpoint high value 830 of 40 ml/min. Similarly, for the low range 820, the operator may specify a setpoint low value 835 of 5 ml/min. In at least one embodiment, the time at which the pump pumps at each of the setpoint high value 830 and the setpoint low value 835 is fixed. In the embodiment shown in Figure 8, however, the time at which the pump will operate at the setpoint values may be adjusted by the operator of the system. For example, as shown in "cycle time" field 850, the pump will operate at each of the setpoint values for one minute. This allows the pump to be calibrated to be most accurate in the range of resuscitation flow rate that is expected to be used.

In at least one embodiment, the operator may also specify a direction for the pump head. For example, depending upon which direction fluid moves through the pump head, a clockwise (CW) or counter-clockwise (CCW) value may be entered into "direction" field 855.

As shown in Figure 8, after calibration begins, the operator may check the status of the calibration via calibration status section 860. The calibration status section 860 displays a total calibration time (beginning at zero and counting up to a selected run time). In an alternative embodiment, the calibration status section 860 displays a total calibration time remaining in "time remaining" field 865. In at least one embodiment, a total calculated delivered volume of fluid is specified in "total volume" field 870 and displayed graphically in real-time in graphical display 875. At the end of the calibration cycle, an actual volume amount resting on the fluid weight balance 215 (shown in Figure 2) is measured. "Measured high" indicator 880 and "Measured low" indicator 885 provide an actual amount of fluid delivered during each cycle. Thus, the operator may compare these values with the setpoints to determine whether to accept the calibration results or discard the calibration results based on the desired accuracy. That is, the setpoint high value 830 is preferably compared with the measured high indicator 880, and the setpoint low value 835 is preferably compared to the measured low indicator 885. If the desired accuracy was not obtained, the operator may choose to run another calibration cycle, as the software will use the current calibration results to perform adjustments for the next calibration run. Regardless of whether the user decides to execute another calibration run or functionally operate the system to resuscitate, the calibration results are saved in the system. It should be noted that the calibration may be aborted at any given time. In at least one embodiment, a previous calibration may be used, as all calibration results are saved in the system until they are cleared from the system.

In at least one embodiment, the system of the present invention is a portable system, which may be utilized by a medic on a battlefield, for instance. For example, as shown in Figure 9, system 900 preferably includes a pump 910, a portable controller 905, an interface box 907,

and the flow rate measurer 115. The illustrated pump 910 is a small battery-powered Power Infuser portable pump.

In at least one embodiment, the portable controller 905 may be a Palm Pilot, a personal digital assistant, or any other viable mobile/portable controller. The system 900 illustrated in Figure 9 is an exemplary test system. In an actual use environment (for example, on a battlefield), however, the interface box 907 would preferably not be an external device as displayed in Figure 9. Rather, the interface box 907 would preferably be a miniature interface connector and reside in the portable controller 905 or alternatively be incorporated into the portable controller 905.

Those having ordinary skill in the art will recognize that the state of the art has progressed to the point where there is little distinction between hardware and software implementations of aspects of systems; the use of hardware or software is generally (but not always, in that in certain contexts the choice between hardware and software can become significant) a design choice representing cost vs. efficiency tradeoffs. Those having ordinary skill in the art will appreciate that there are various vehicles by which processes and/or systems described herein can be effected (for example, hardware, software, and/or firmware), and that the preferred vehicle will vary with the context in which the processes are deployed. For example, if an implementer determines that speed and accuracy are paramount, the implementer may opt for a hardware and/or firmware vehicle; alternatively, if flexibility is paramount, the implementer may opt for a solely software implementation; or, yet again alternatively, the implementer may opt for some combination of hardware, software, and/or firmware. Hence, there are several possible vehicles by which the processes described herein may be effected, none of which is inherently superior to the other in that any vehicle to be utilized is a choice dependent upon the context in which the vehicle will be deployed and the specific concerns (e.g., speed, flexibility, or predictability) of the implementer, any of which may vary.

The foregoing detailed description has set forth various embodiments of the devices and/or processes via the use of block diagrams, flowcharts, and examples. Insofar as such block diagrams, flowcharts, and examples contain one or more functions and/or operations, it will be understood by those within the art that each function and/or operation within such block diagrams, flowcharts, or examples can be implemented, individually and/or collectively, by a wide range of hardware, software, firmware, or any combination thereof (or means for performing the respective function and/or operation). However, those skilled in the art will recognize that the embodiments disclosed herein, in whole or in part, can be equivalently implemented in standard Integrated Circuits, via Application Specific Integrated Circuits (ASICs), as one or more computer programs running on one or more computers (for example, as one or more server programs running on one or more computer systems), as one or more programs running on one or more processors (for example, as one or more thin client programs

13

running on one or more processors), as firmware, or as virtually any combination thereof, and that designing the circuitry and/or writing the code for the software or firmware would be well within the skill of one of ordinary skill in the art in light of this disclosure. In addition, those skilled in the art will appreciate that the mechanisms of the present invention are capable of being distributed as a program product in a variety of forms, and that an illustrative embodiment of the present invention applies equally regardless of the particular type of signal bearing media used to actually carry out the distribution. Examples of a signal bearing media include, but are not limited to, the following: recordable type media such as floppy disks, hard disk drives, CD ROMs, digital tape, and transmission type media such as digital and analogue communication links using TDM or IP based communication links (for example, packet links).

The exemplary and alternative embodiments described above may be combined in a variety of ways with each other. Furthermore, the dimensions, shapes, sizes, and number of the various pieces illustrated in the figures may be adjusted from that shown.

Although the present invention has been described in terms of particular exemplary and alternative embodiments, it is not limited to those embodiments. Alternative embodiments, examples, and modifications which would still be encompassed by the invention may be made by those skilled in the art, particularly in light of the foregoing teachings.

Those skilled in the art will appreciate that various adaptations and modifications of the exemplary and alternative embodiments described above can be configured without departing from the scope and spirit of the invention. Therefore, it is to be understood that, within the scope of the appended claims, the invention may be practiced other than as specifically described herein.

IN THE CLAIMS:

We claim:

1.   An automated system for controlling resuscitation of a patient, comprising:

a fluid rate measurer;

at least one pump;

a physiological monitor;

a controller electrically coupled to said fluid rate measurer, said physiological monitor, and said at least one pump, said controller adapted to receive signals transmitted by said physiological monitor and capable of executing

a servo control computer program module for receiving values specifying a physiological variable range and controlling said at least one pump; and

an error correction computer program module for performing error correction of the voltage to control said pump based on a relation of an amount of fluid expected to be pumped and an amount of fluid that is actually pumped by said pump.

2.   The automated system of claim 1, further comprising a calibration module for performing an initial fluid flow rate calibration to determine a relationship between pumping volume and pumping voltage.

3.   The automated system of claim 1 or 2, wherein said servo control computer program module includes computer readable instructions for allowing an operator to specify a low value for the physiological variable range.

4.   The automated system of claim 1, 2, or 3, wherein said servo control computer program module further includes computer readable instructions for allowing an operator to specify a high value for the physiological variable range.

5.   The automated system of claim 4, wherein said resuscitation pump begins to pump only when the signal from said physiological monitor approaches or reaches the low value consecutively for two data collection cycles and ceases to pump only when the signal from said physiological monitor approaches or reaches said high value consecutively for two data collection cycles.

6.   The automated system of any of claims 1-5, wherein said controller receives a signal representing the physiological variable in five second intervals during operation of the system.

7.   The automated system of any of claims 1-6, wherein said error correction computer program module includes

a first set of computer readable instructions for receiving an expected relation of volume and time according to which the system should operate;

a second set of computer readable instructions for converting the expected relation of volume and time to a pumping voltage according to which said at least one pump is operated;

a third set of computer readable instructions for receiving a specific gravity of a fluid value;

a fourth set of computer readable instructions for utilizing the specific gravity of a fluid value to convert the expected relation to an expected fluid weight measurement;

a fifth set of computer readable instructions for receiving an actual fluid weight measurement; and

a sixth set of computer readable instructions for comparing the actual fluid weight measurement with the expected fluid weight measurement.

8.   The automated system of any of claims 1-6, wherein said error correction computer program module includes determining a rate based on a difference between a level of fluid in a container weighed by said fluid rate measurer and an expected level of fluid to be in the container if the system were pumping as expected.

9.   The automated system of any of claims 1-8, wherein said controller resides on a personal digital assistant (PDA).

10.   The automated system of any of claims 1-8 wherein said pump includes a rotary infusion pump.

11.   The automated system of any of claims 1-8, wherein said pump includes a Power Infuser resuscitation pump.

12.   The automated system of any of claims 1-11, wherein said flow rate measurer includes a flow meter.

13.   The automated system of any of claims 1, 2, or 6-12, wherein the physiological variable range is adjusted over time based on a predetermine resuscitation profile.

14.   A system for controlling resuscitation of a patient and connecting to a physiological monitor attached to the patient, said system comprising:

a measuring means for measuring a representation of fluid rate;

a pumping means for pumping resuscitation fluid into the patient;

an error correction means for performing error correction of said pumping means based on a relation of an amount of fluid expected to be pumped and an amount of fluid that is actually pumped by said pumping means as represented by signals received from said measuring means; and

a controlling means for automatically controlling said pumping means based on signals received from the physiological monitor and signal received from said error correction means.

15.   The system of claim 14, further comprising a means for calibrating fluid flow rate to determine a relationship between pumping volume and pumping voltage.

16.   The system of claim 14 or 15, wherein said controlling means includes means for allowing an operator to specify a low value for a physiological variable range.

17.   The system of claim 16, wherein said controlling means further includes means for allowing an operator to specify a high value for the physiological variable range.

18.   The system of any of claims 14-17, wherein said controlling means sends a signal to said pumping means to begin pumping only when the physiological variable reaches or is lower than the low value consecutively for two data collection cycles and a signal to cease pumping only when the physiological variable reaches or exceeds the high value consecutively for two data collection cycles.

19.   The system of any of claims 14-18, wherein said controlling means polls the physiological monitor in five second intervals.

20.   The system of any of claims 14-19, wherein said error correction means includes
    means for receiving an expected relation of volume and time according to which the system should operate;
    means for converting said expected relation of volume and time to a pumping voltage according to which said pumping means is operated;
    means for receiving a specific gravity of a fluid value;
    means for utilizing the specific gravity of a fluid value to convert the expected relation to an expected fluid weight measurement;
    means for receiving an actual fluid weight measurement; and
    means for comparing the actual fluid weight measurement with the expected fluid weight measurement.

21.   The system of any of claims 14-19, wherein said error correction means includes means for determining a rate based on a difference between the level of fluid in a container weighed by said measuring means and the expected level of fluid to be in the container if the system were pumping as expected.

22.   A medical system for controlling resuscitation of a patient comprising:
    the system of any of claims 14-21, and
    a physiological monitor adapted to be coupled with said system.

23.   A method for controlling resuscitation of a patient connected to a physiological monitor, the method comprising:

receiving a physiological signal from a physiological monitor, the physiological signal is indicative of a physiological variable,

sending a pumping signal to a pump based upon whether the physiological variable is below a target range for the physiological variable,

receiving a flow signal from a measuring device, the flow signal is indicative of the rate at which the resuscitation fluid is being pumped into the patient; and

performing error correction of the pumping signal based on the difference between an amount of fluid expected to be pumped and an amount of fluid that is actually pumped.

24.   The method of claim 23, receiving a low value and a high value for the target range for the physiological variable.

25.   The method of claim 23 or 24, wherein said pumping begins only when the physiological variable is equal to or lesser than the low value consecutively for two data collection cycles and ends only when the physiological variable is equal to or greater than high value consecutively for two data collection cycles.

26.   The method of any of claims 23-25, wherein receiving a physiological signal occurs in five second intervals during operation.

27.   The method of any of claims 23-26, wherein said performing error correction includes

receiving an expected relation of volume and time according to which the system should operate;

. converting said expected relation of volume and time to a pumping voltage according to which pumping is performed;

receiving a specific gravity of a fluid indication;

utilizing the specific gravity of a fluid indication to convert the expected relation to an expected fluid weight measurement;

receiving an actual fluid weight measurement; and

comparing the actual fluid weight measurement with the expected fluid weight measurement.

28.   The method of any of claims 23 or 25-27, wherein the target range of the physiological variable adjusts over time along a predetermined profile.

29.   A data signal embodied in a carrier wave readable by a computing system and encoding instructions for executing a process performing the method recited in any of claims 23-28.

30.   A computer-readable medium having computer-executable instructions for the method recited in any of claims 23-28.

31.   A controller for controlling resuscitation of a patient, comprising:

means for receiving input from a fluid rate measurer;

means for receiving input from at least one pump;

means for receiving values specifying a physiological variable range and controlling the at least one pump; and

means for performing error correction of voltage to control the at least one pump based on a relation of an amount of fluid expected to be pumped and an amount of fluid that is actually pumped by the pump.

32.   The controller of claim 31, further comprising means for receiving input from a physiological monitor.

33.   The controller of claim 31 or 32, wherein the physiological variable range is adjusted over time based on a profile.

34.   The system of any of claims 31-33, wherein said error correction means includes

means for receiving an expected relation of volume and time according to which the system should operate;

means for converting said expected relation of volume and time to a pumping voltage according to which said pumping means is operated;

means for receiving a specific gravity of a fluid value;

means for utilizing the specific gravity of a fluid value to convert the expected relation to an expected fluid weight measurement;

means for receiving an actual fluid weight measurement; and

means for comparing the actual fluid weight measurement with the expected fluid weight measurement.

35.   The system of any of claims 31-33, wherein said error correction means includes means for determining a rate based on a difference between the level of fluid in a container weighed by said measuring means and the expected level of fluid to be in the container if the system were pumping as expected.

36.   A medical system for controlling resuscitation of a patient comprising:

the system of any of claims 31-35, and

19

a physiological monitor adapted to be coupled with said system.

37.   An automated resuscitation device being substantially as herein described with reference to the accompanying figures.

38.   An automated resuscitation method being substantially as herein described with reference to the accompanying figures.
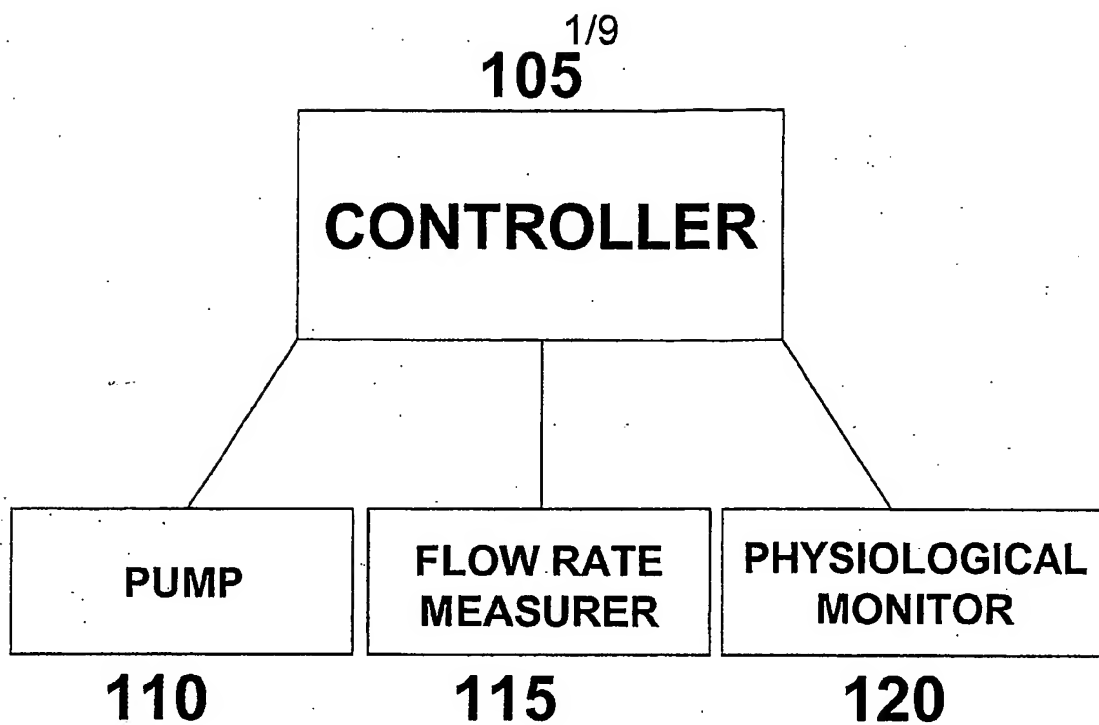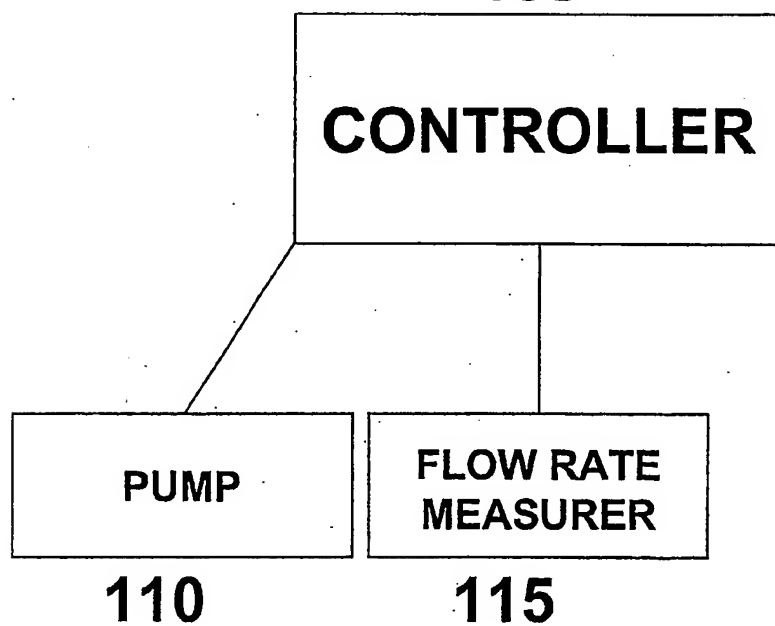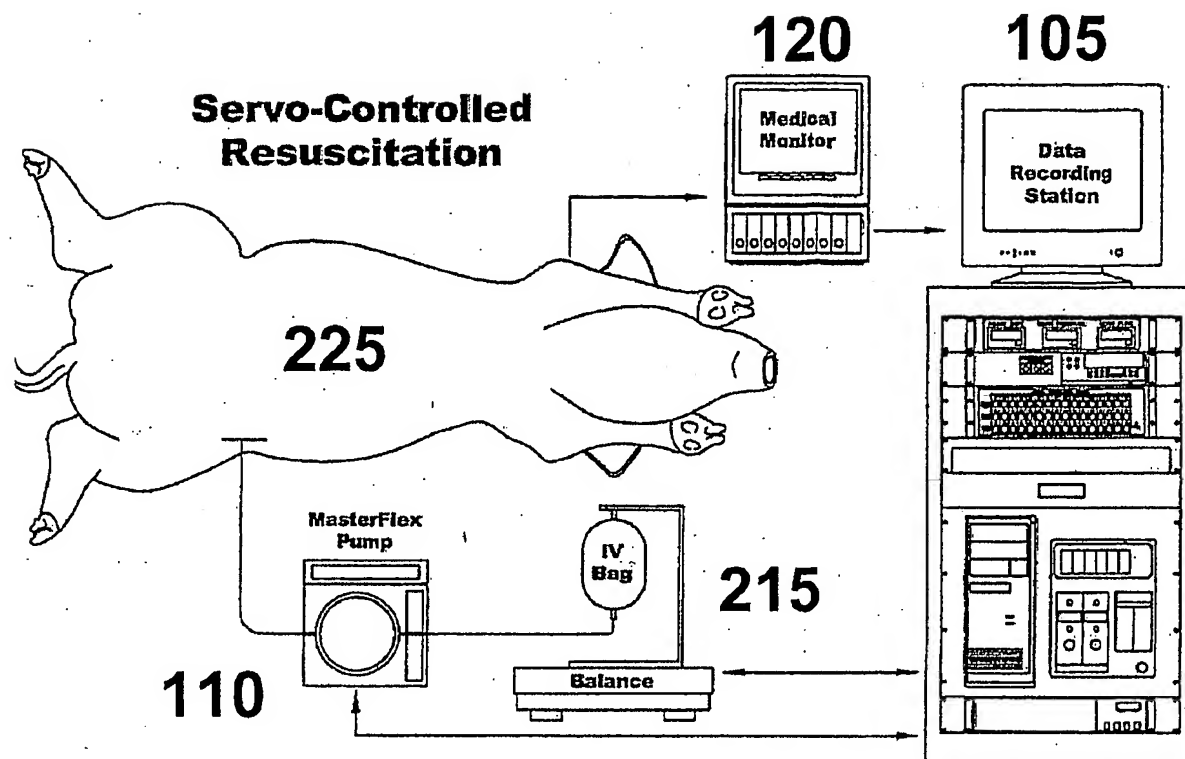
105

CONTROLLER

PUMP

FLOW RATE MEASURER

PHYSIOLOGICAL MONITOR

110

115

120

FIGURE 1A

105

CONTROLLER

PUMP

FLOW RATE MEASURER

110

115

FIGURE 1B

FIGURE 2

FIGURE 3

FIGURE 4

5/9

```
┌─────────────────────────────────────────────────────────────┐
│                            550                                │
│   Receiving a physiological signal from a physiological monitor│
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            555                                │
│           Transmitting a pumping signal to a pump             │
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            560                                │
│        Receiving a flow signal from a fluid-rate measurer     │
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            565                                │
│                   Performing error correction                 │
└─────────────────────────────────────────────────────────────┘
```

FIGURE 5A

```
┌─────────────────────────────────────────────────────────────┐
│                            505                                │
│  Receive an expected relation of volume and time according to which the│
│                    system should operate                      │
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            510                                │
│  Convert the expected relation of volume and time to a pumping voltage│
│     according to which the resuscitation pump is operated     │
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            515                                │
│                 Receive specific gravity of fluid             │
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            520                                │
│  Utilize the specific gravity to convert the expected relation to an expected│
│                   fluid weight measurement                    │
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            525                                │
│             Receive actual fluid weight measurement           │
└─────────────────────────────────────────────────────────────┘
                              │
                              ▼
┌─────────────────────────────────────────────────────────────┐
│                            530                                │
│  Compare the actual fluid weight measurement with the expected relation of│
│    volume and time according to which the system should operate│
└─────────────────────────────────────────────────────────────┘
```

FIGURE 5B

610

630

635

640

FIGURE 6

717   **710**

716

705

715
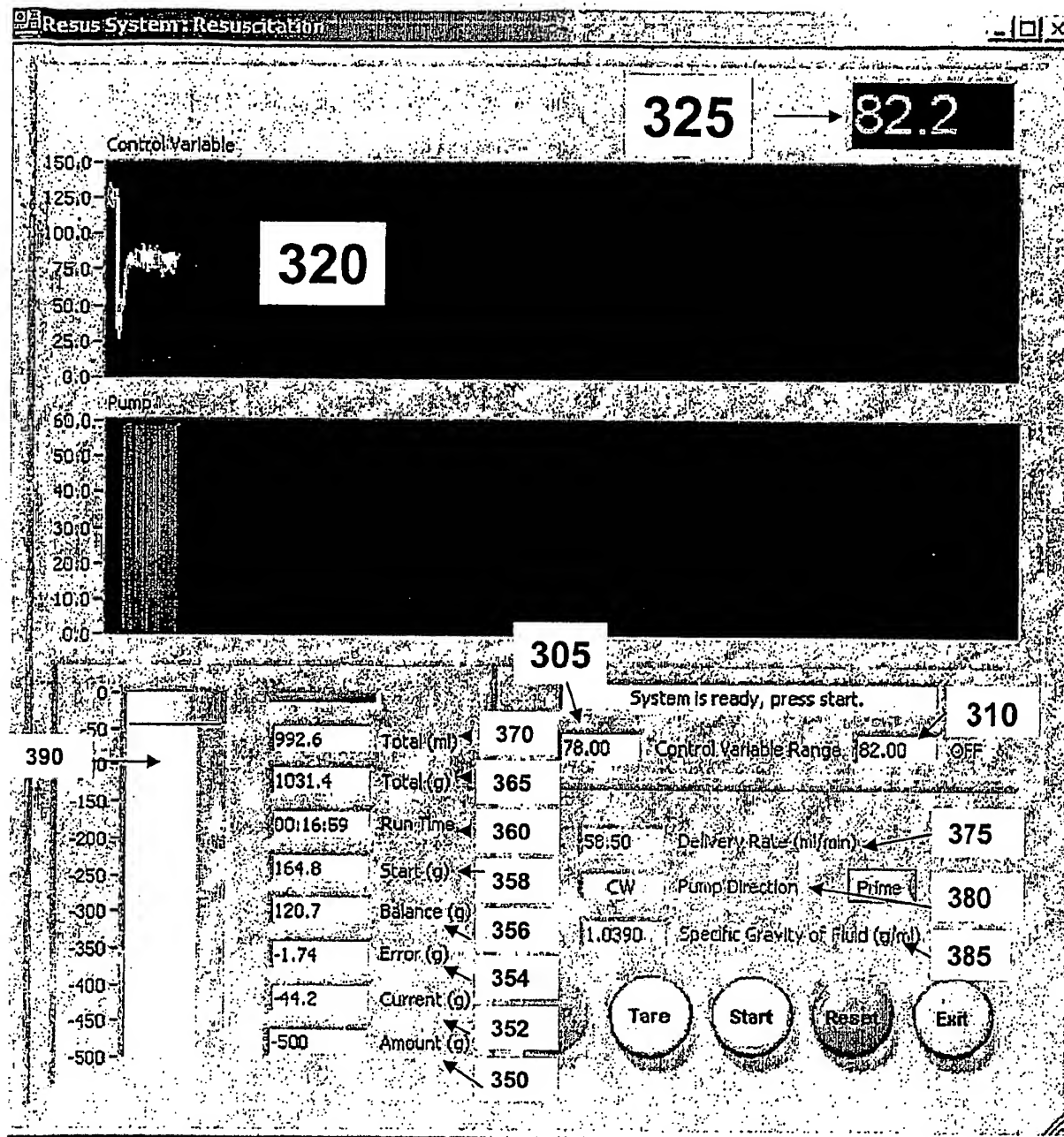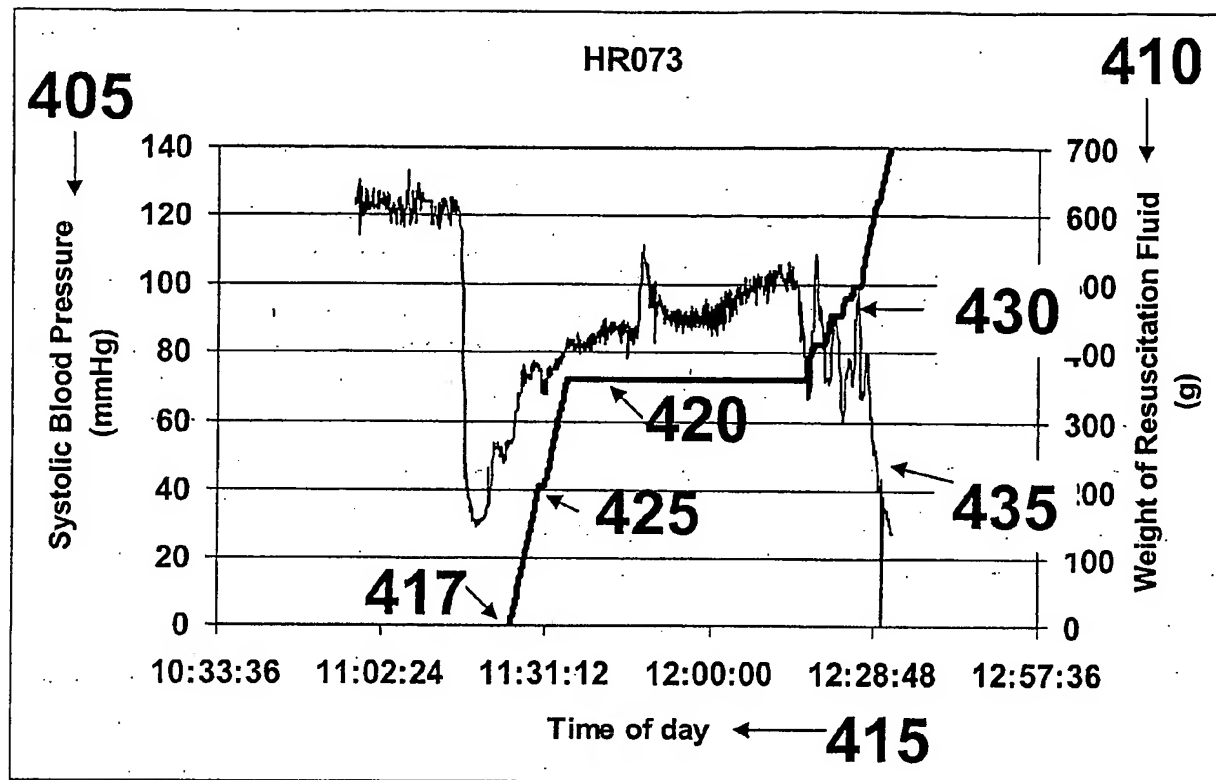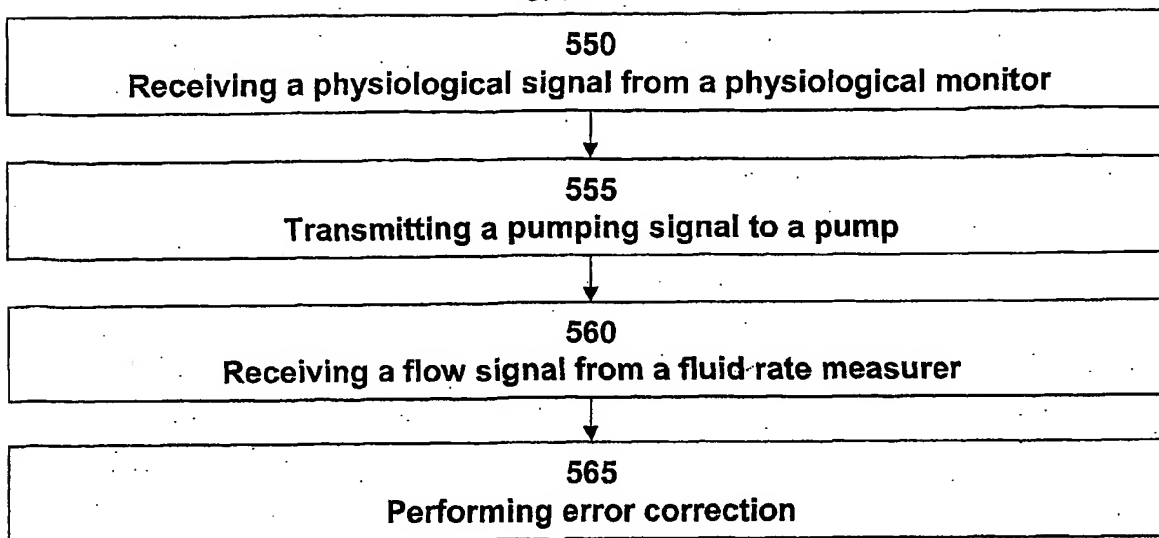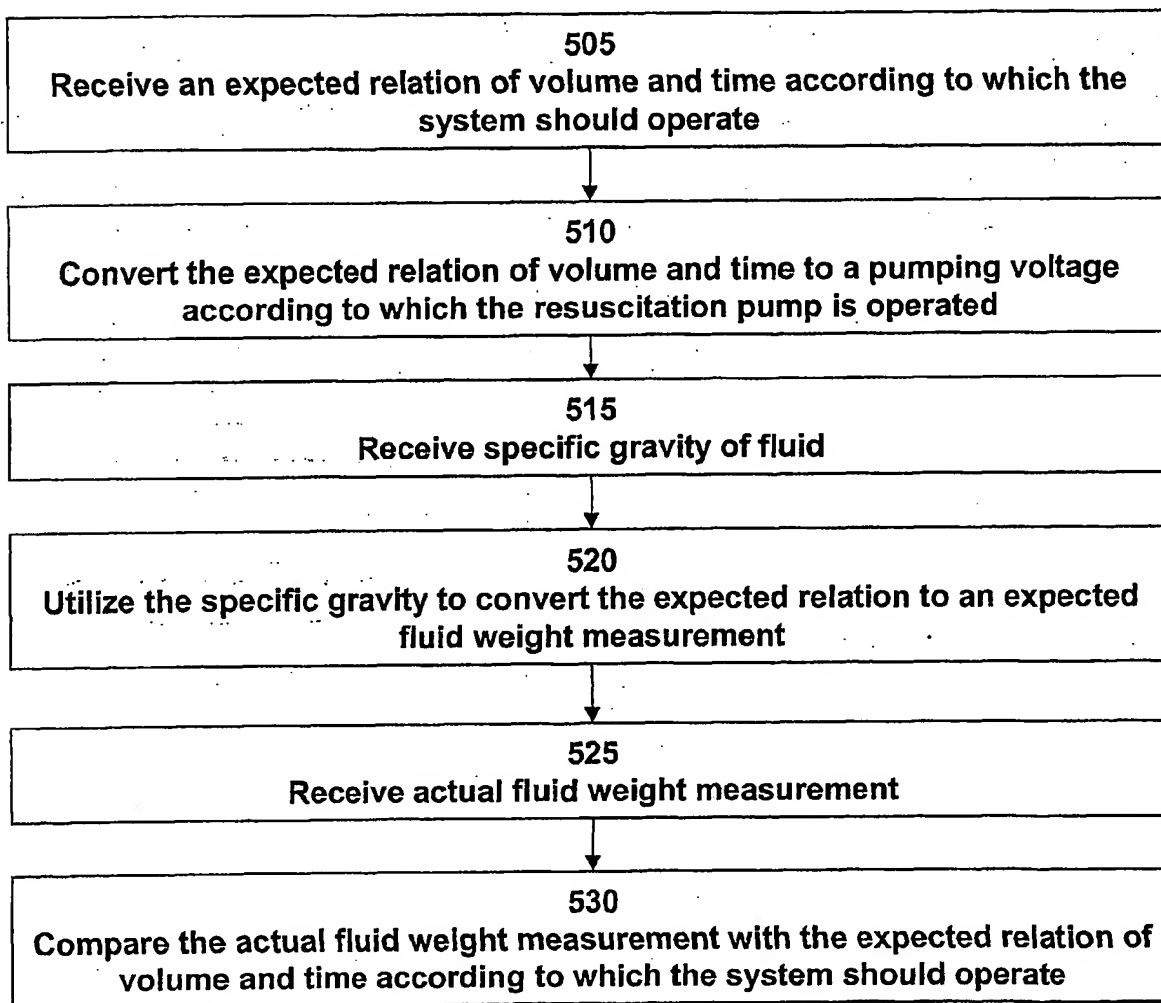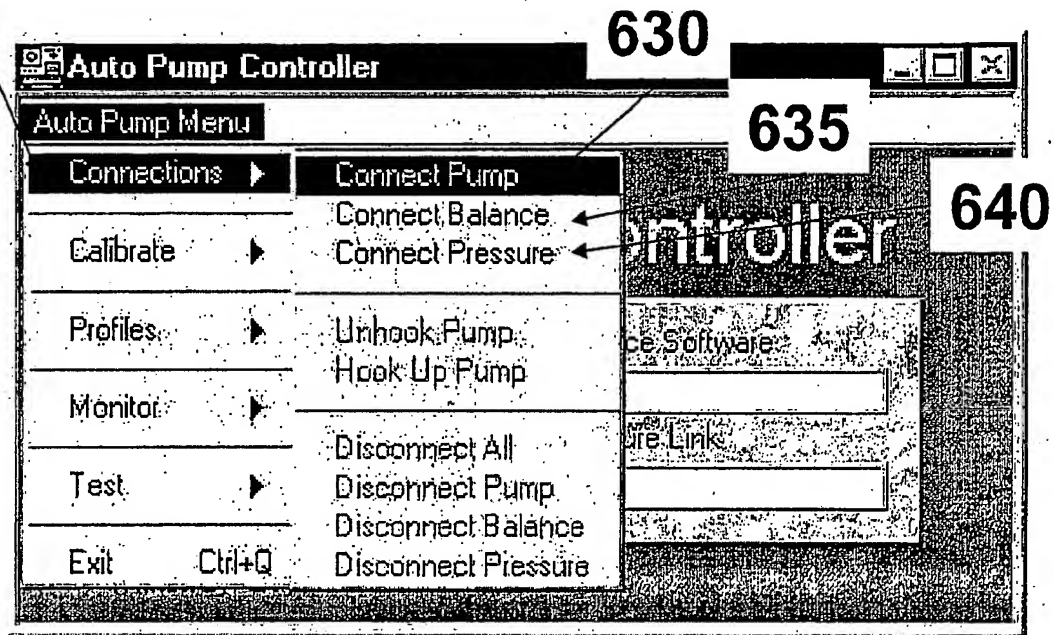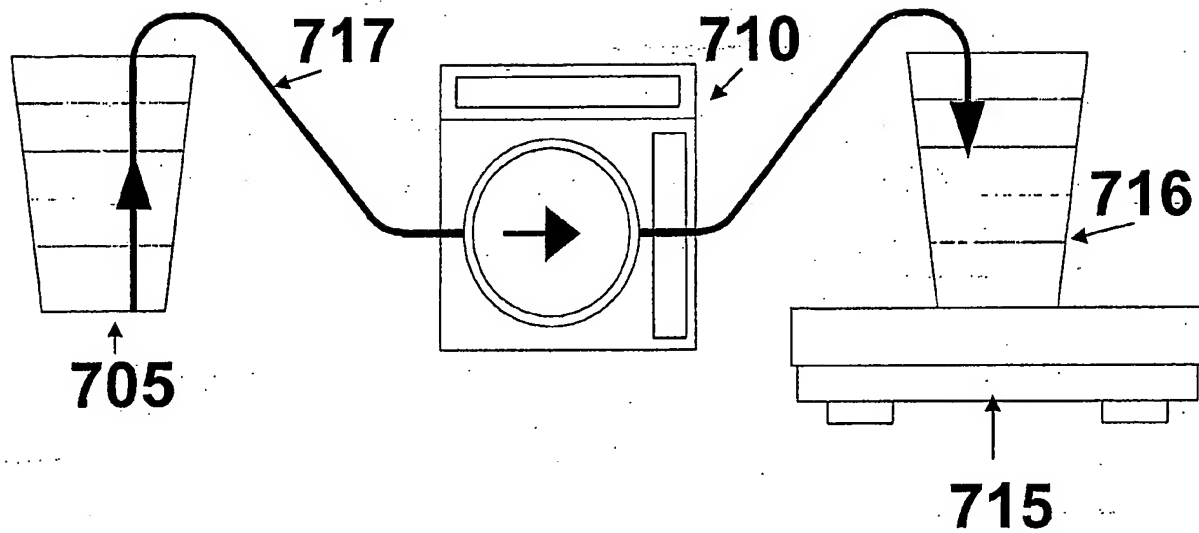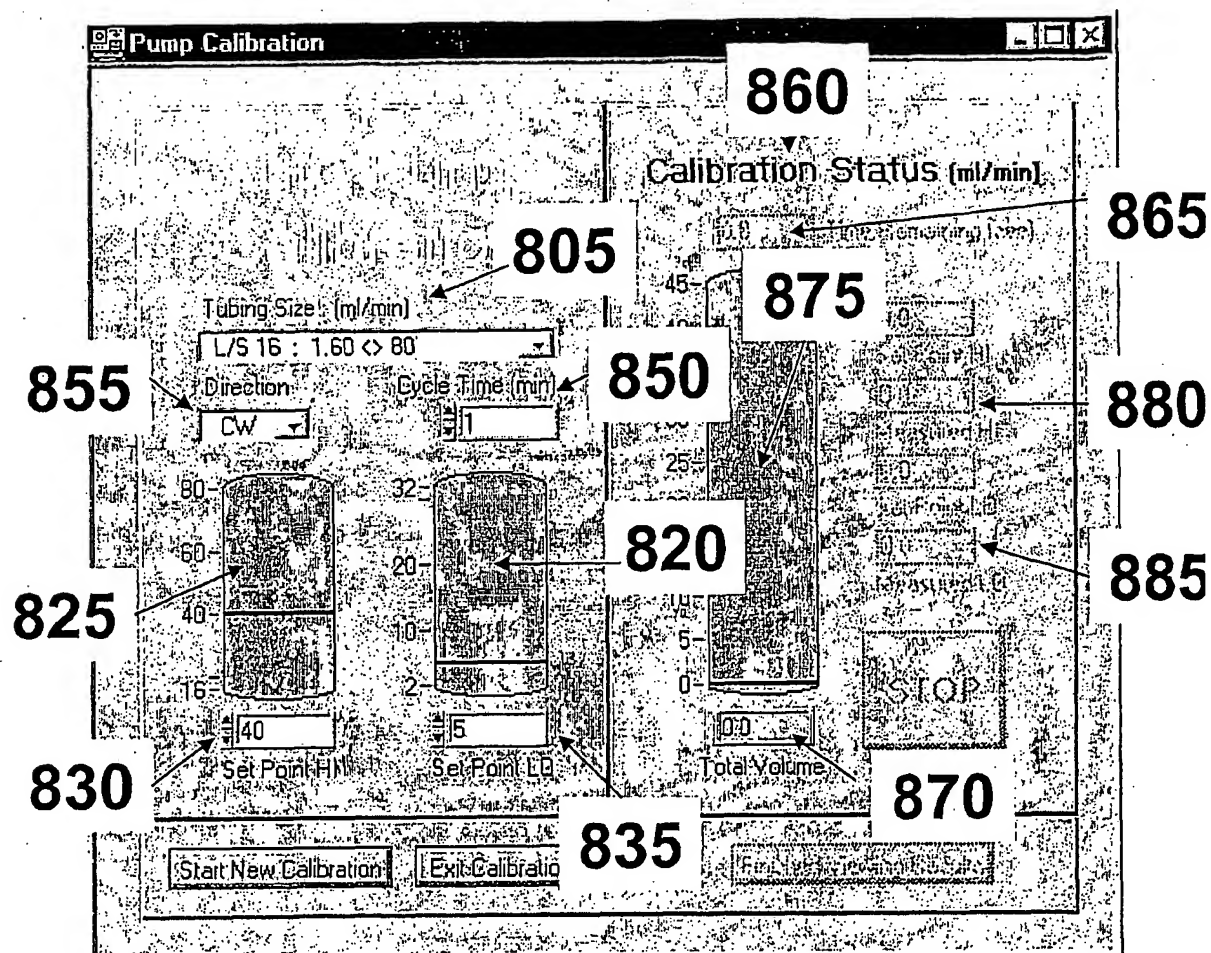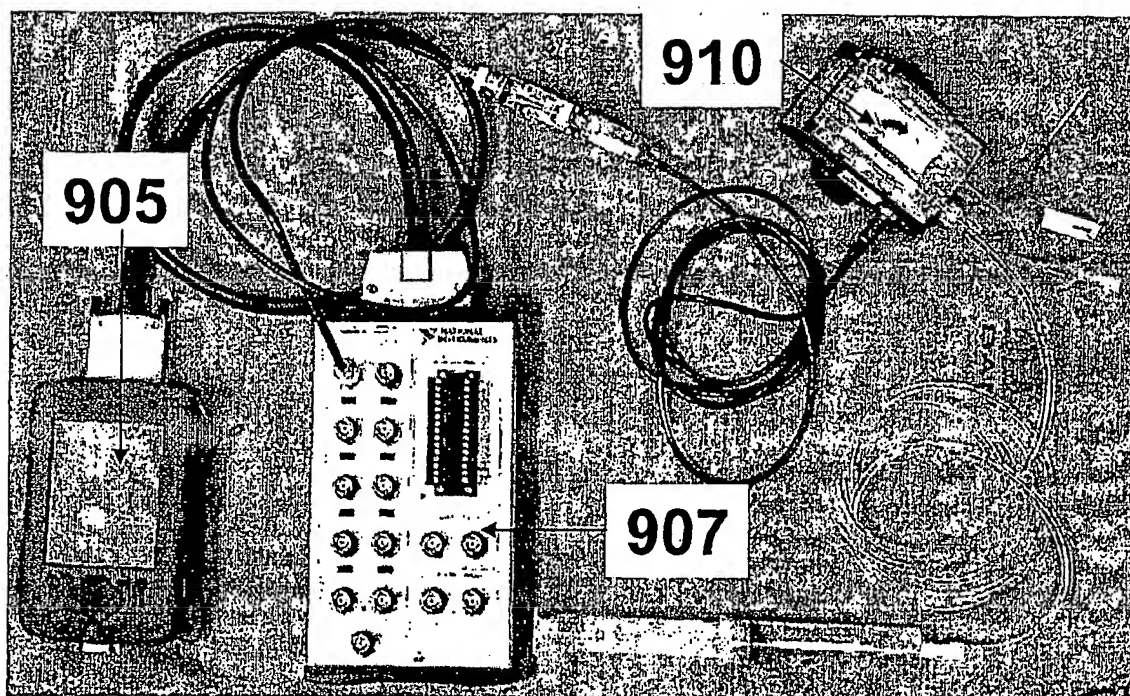
FIGURE 7

FIGURE 8

FIGURE 9

(51) International Patent Classification⁷: A61M 31/00

(21) International Application Number:
PCT/US2004/029111

(22) International Filing Date:
8 September 2004 (08.09.2004)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
60/500,889   8 September 2003 (08.09.2003)   US

(71) Applicant (for all designated States except US): U.S. GOVERNMENT AS REPRESENTED BY THE SEC-RETARY OF THE ARMY [US/US]; Office of the Staff Judge Advocate, U.S. Army Institute of Surgical Research, Attn: MCMR-JA (Ms. Elizabeth Arwine), 504 Scott Street, Fort Detrick, Maryland 21702-5012 (US).

(72) Inventors; and
(75) Inventors/Applicants (for US only): SONDEEN, JIll, L. [US/US]; P.O. Box 310048, New Braunfels, Texas 78131 (US). DREW, Guy, A. [US/US]; 14521 Waddesdon Bluff, San Antonio, Texas 78233 (US).

(74) Agents: ARWINE, Elizabeth et al; Office of the Staff Judge Advocate, Department of the Army, U.S. Army Medical Research and Materiel Command, 504 Scott Street, Fort Derrick, Maryland 21702-5012 (US).

(81) Designated States (unless otherwise indicated, for every kind of national protection available): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BW, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, EG, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NA, NI, NO, NZ, OM, PG, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, SY, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW

(84) Designated States (unless otherwise indicated, for every kind of regional protection available): ARIPO (BW, GH, GM, KE, LS, MW, MZ, NA, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PL, PT, RO, SE, SI, SK, TR), OAPI (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

(54) Title: SYSTEM AND METHOD FOR PROVIDING SERVO-CONTROLLED RESUSCITATION

(57) Abstract: The present invention provides a system and method for controlling resuscitation in a patient. In at least one embodiment, the invention includes a fluid rate measurer, a controller electrically coupled to the fluid rate measurer, and a pump. The controller is adapted to receive signals from a physiological monitor and controls the pump.

— *before the expiration of the time limit for amending the claims and to be republished in the event of receipt of amendments*

(88) **Date of publication of the international search report:**
20 April 2006

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/291 11

A.	CLASSIFICATION OF SUBJECT MATTER

IPC(7)   :   A61M 31/00
US CL   :   604/65

According to International Patent Classification (IPC) or to both national classification and IPC

B.	FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
    U.S. : 604/65, 66, 67, 131

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C.	DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A,P	US 6694977 B1 (FEDEROWICZ ET AL.) 24 FEBRUARY 2004 NOTE: PLEASE REVIEW THE ENTIRE PATENT.	1-38

☐ Further documents are listed in the continuation of Box C.   ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance		
"E"	earlier application or patent published on or after the international filing date	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed	"&"	document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
0 1 February 2006 (01.02.2006)	24 FEB 2006

Name and mailing address of the ISA/US
    Mail Stop PCT, Attn: ISA/US
    Commissioner for Patents
    P.O. Box 1450
    Alexandria, Virginia 22313-1450
Facsimile No. (571) 273-3201
	Authorized officer
	Manuel Mendez
	
	Telephone No. 703-000-000

Form PCT/ISA/210 (second sheet) (April 2005)